

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 09/973,088
Applicant : Marie B. CONNETT-PORCEDDU
Filed : 10 October 2001
TC/A.U. : 1638
Examiner : Stuart F. Baum

Confirmation No. 4800

Docket No. : 2411-110
Customer No. : 6449

COPY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER RULE 132 OF JAMES E. MANN

Dear Sir:

I, James E. Mann, declare as follows:

1. My education and experience are as follows. I received a Bachelor of Science degree in Biology and Chemistry from Shorter College in 1991, a Masters of Science degree in Entomology from Clemson University in 1993, a Doctorate degree in Entomology from Clemson University in 1995 and a Masters of Business Administration from the University of Missouri in 2001. I have been employed by ArborGen, LLC, which is a joint venture including Westvaco Corporation, the assignee of the present application, from 2001 to present as a Director, Finance and Business Development. I was employed by Monsanto Company from 1996 to 2001, first as a Marketing Manager and then as Director, Business Development.

2. While at Monsanto, I led the marketing and business development efforts for biotech cotton in the United States, Mexico and Australia. At ArborGen, I am responsible for leading all business development and licensing activities, including our current somatic embryogenesis production business, which includes somatic embryogenesis of transgenic tissue. My professional background and experience have given me a good and understanding of conifer somatic embryogenesis production and its commercial potential. Accordingly, I believe that I am well

qualified to render a professional opinion regarding the commercial success of conifer somatic embryogenesis of conifers, including transgenic conifers.

3. I understand that the claims recite (a) a method for regenerating transgenic plants of pine of the genus *Pinus* subgenus *Pinus* (claims 1-9 and 11-38), (b) a method for minimizing damage to transformed cell of the pine of the genus *Pinus* subgenus *Pinus* following infection by *Agrobacterium* (claims 39-43 and 45), (c) a method for pine cell tissue culture of pine cells of the genus *Pinus* subgenus *Pinus* (claims 46-51), (d) a method for selecting transformed cells of pine of the genus *Pinus* subgenus *Pinus* (claims 52-57), and (e) a method for eradicating *Agrobacterium* from cells of pine of the genus *Pinus* subgenus *Pinus* (claims 58-62). The method of claims 1-9 and 11-38 provides for enhanced transformation and regeneration of transformed embryogenic pine tissue in which the pine is of the genus *Pinus* subgenus *Pinus*. The remaining methods relate to various aspect of this method. I also understand that the claims of related copending patent application Serial No. 09/973,089 recite a method for regenerating genetically modified plants of pine of the genus *Pinus* selected from the group consisting of Southern yellow pines and hybrids thereof using an improved selection method. This method provides for enhanced regeneration of transgenic embryogenic pine cells for this important group of pines.

4. I understand that the Examiner contends that the invention of the present application, regeneration of transformed embryogenic hard pine (i.e., pines of the subgenus *Pinus*, e.g., *Pinus taeda*), would have been obvious over Levee et al. (*Molecular Breeding* 5:429-440, 1999) which describes the regeneration of transformed embryogenic soft pine (i.e., pines of the subgenus *Strobus*, e.g., *Pinus strobus*). I also have been advised that Levee et al. does not disclose the transformation and regeneration of pine of the subgenus *Pinus*.

5. I have been asked to provide this Declaration concerning commercial success of the methods described and claimed in the present application, as well as those described and claimed in patent application Serial No. 09/973,089.

6. The hard pines (i.e., pines of the subgenus *Pinus*), in particular loblolly pine (*P. taeda*, a Southern yellow pine), its elite lines and hybrids, but also including *P. rigida* and *P. radiata*, are the most commercially important pines, and loblolly pine is the most used species of hard pines. Specifically, loblolly pine is the most widely planted plantation forest species in the world with over

one billion trees planted annually in more than half a dozen countries worldwide. Radiata pine is equally important with over four million hectares already in industrial plantations in more than half a dozen countries worldwide.

7. I have reviewed the Declaration Under Rule 132 of Dr. David Canavera (that is being filed concurrently herewith) concerning the long-felt need in the art for the transformation and regeneration of transformed tissue of pines of the subgenus *Pinus* and the failed attempts of others to meet this need. I agree with his opinion that there was a long felt need to develop improved methods of *Agrobacterium* transformation of hard pines and improved selection of transformed tissue of hard pines, and to develop methods to regenerate *Agrobacterium*-transformed hard pines. I also agree with his opinion that this long felt need was not satisfied by transformation of other conifers, such as white pines and spruces, but was only satisfied by the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089.

8. In addition, ArborGen since its founding has wanted to obtain protocols that would lead to a robust, commercializable system for repeatable, reliable pine transformation followed by efficient selection and embryo development/regeneration, and would be willing to use such protocols developed by anyone. However, since such protocols do not exist elsewhere, including within universities, such as North Carolina State University, institutions, such as Institute of Paper Science and Technology, or the Canadian Forest Service, ArborGen has licensed the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089.

9. ArborGen is using these methods in (a) pre-commercial trials toward the development of ArborGen's commercial products in improved pulping and (b) a gene testing pipeline that is unique because up to 30-60 genes involved in wood development per year can be tested repeatedly in elite genotypes of a conifer species. ArborGen is managing and actively measuring and using field trials, on two different managed field sites and in propagation hedges, of pine plants that arose from material cultured, transformed, selected and embryos developed and regenerated according to the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089.

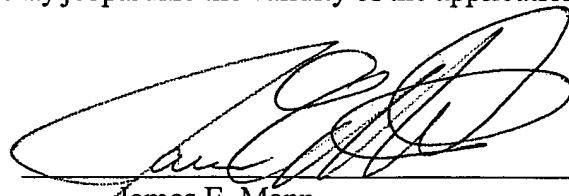
10. In addition to ArborGen's licensing and commercial use of the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089, ArborGen has been approached by other researchers desiring deals in which ArborGen would use the methods described

and claimed in patent application Serial Nos. 09/973,088 and 09/973,089 to prepare transgenic hard pines with the genes of interest to these researchers in order to test the expression of genes in pine, especially loblolly pine. These researchers include researchers from a variety of U.S. universities, including North Carolina State University and the University of Florida, researchers from the Canadian Forest Service and Institute of Paper Science and Technology, researchers at European universities and researchers from private companies. For example, ArborGen has been approached by researchers who are interested in downregulating a certain gene using RNAi. In order to do RNAi on a pine gene, these researchers need to have working pine transformation system which is only available by the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089. The fact that various researchers have approached ArborGen about using the transformation system of the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089 is evidence of the commercial value of these methods and is also further evidence that there is no other efficient method to for pine transformation and regeneration of transformed tissue.

11. These facts demonstrate the commercial success of methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089.

12. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or of any patent issued thereon.

4/13/04
Date


James E. Mann